



PATENT APPLICATION AF/IFW

PATENT AND TRADEMARK OFFICE

BEFORE THE HONORABLE BOARD OF PATENT APPEALS AND INTERFERENCES

In re the Application of

Jean-Noel THOREL

Application No.: 10/006,389

On Appeal from Group: 1655

Examiner: S. HOFFMAN

Filed: December 10, 2001

Docket No.: 108961.01

For: COSMETIC PRODUCTS COMPATIBLE WITH CUTANEOUS ECOLOGY AND
METHODS FOR THEIR USE

APPEAL BRIEF TRANSMITTAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Attached hereto is our Brief on Appeal in the above-identified application.

Also attached hereto is our Check No. 193053 in the amount of Five Hundred Dollars (\$500.00) in payment of the Brief fee under 37 C.F.R. 41.20((b)(2)). In the event of any underpayment or overpayment, please debit or credit our Deposit Account No. 15-0461 as needed in order to effect proper filing of this Brief.

Respectfully submitted,

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BRIEF ON APPEAL

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Appeal from Group 1600

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I. REAL PARTY IN INTEREST

The real party in interest for this appeal and the present application is the inventor Jean-Noel Thorel. The present application is not assigned to, or subject of assignment to, any other party.

II. RELATED APPEALS AND INTERFERENCES

There are no prior or pending appeals, interferences or judicial proceedings, known to Appellant or Appellant's representative, that may be related to, or that will directly affect or be directly affected by or have a bearing upon, the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 1-3, 5-8, 12, 16, 18-20, 23 and 29 are on appeal.

Claims 1-3, 5-8, 12, 16, 18-20, 23 and 29 are pending.

Claims 1-3, 5-8, 12, 16, 18-20, 23 and 29 are rejected.

No claims are allowed.

Claims 4, 9-11, 13-15, 17, 21, 22, 24-28 and 30-35 are canceled.

IV. STATUS OF AMENDMENTS

No Amendment After Final Rejection has been filed.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Claim 1 recites a cosmetic or dermo-therapeutic composition for a direct application onto surface parts of the human body, in a form adapted for said direct application, said composition comprising: a biodermal fraction representing 98-100% by weight of the composition, comprising at least two different biodermal constituents, each being cytocompatible with skin; and a non-biodermal fraction representing 0-2% by weight of the composition, comprising at least one non-biodermal constituent that is compatible with skin, said composition having no excipient or vehicle adapted to said form of the composition, wherein, if water is one of the constituents, it is part of the biodermal fraction and represents a minor part by weight of said composition. Dependent claims 2-3, 5-8, 12, 16, 18-20, 23 and 29 include features further specifying the components of the claimed composition.

Accordingly, the subject matter of the pending claims is directed to cosmetic or dermatological products. Conventionally, as shown by U.S. Patent No. 5,508,034 to Bernstein (hereinafter "Bernstein") and U.S. Patent No. 5,886,041 to Yu et al. (hereinafter "Yu") cosmetic or dermatological products are manufactured like any other pharmaceutical product, *i.e.*, consisting of (1) an active ingredient or component (active principle) and (2) a vehicle (excipient). The active principle is the separable part that exerts a beneficial action or result on an exterior portion of the human body, for example the skin. The excipient functions to confer to the final product stabilizing form to facilitate delivery of the active principle, for example, as an oil and water emulsion, lotion, gel or cream. The excipient facilitates topical application of the cosmetic or dermatological product, but otherwise providing no beneficial action or result.

A cosmetic or dermatological product according to the claimed subject matter is made of components, which cannot be classified as or categorized between an active principle and an excipient. As disclosed in col. 2, lines 56-63, each disclosed component, or any

combination thereof, behaves as an active principle, *e.g.*, for treating the skin, and as an excipient for creating a suitable and stable topical form for the application of the product.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The following grounds of rejection are presented for review:

- 1) Claims 1-3, 5-8, 12, 16, 18-20, 23 and 29 are rejected under 35 U.S.C. §102(b) as being anticipated over U.S. Patent No. 5,508,034 to Bernstein (hereinafter "Bernstein").
- 2) Claims 1, 9-11 and 13 are rejected under 35 U.S.C. §103(a) as being unpatentable over Bernstein.
- 3) Claims 1, 9-11, 16, 21 and 22 are rejected under 35 U.S.C. §103(a) as being unpatentable over Bernstein in view of U.S. Patent No. 5,886,041 to Yu et al. (hereinafter "Yu").

VII. ARGUMENT

The claimed subject matter is concerned with a final product, *i.e.*, a product that is suitable to be applied topically on skin. A prior art reference disclosing an intermediate product not in a form suitable for topical application cannot reasonably be considered to teach, or to have suggested, the claimed final product even if the intermediate product of the prior art contains more than 98% weight percent active principle but the final product of the prior art has less than 98% weight percent active principle because a skilled artisan would understand that only the final and not the intermediate product is topically applied as a cosmetic or a dermo-therapeutic composition.

Throughout prosecution of this application, Appellant argued the features positively recited in the pending claims. Instead of providing support for its assertions from one Office Action, the Patent Office applied new references in subsequent Office Actions suffering from the same deficiencies as the references applied in previous Office Actions. The Patent Office's failure to find and apply any reference that teaches the claimed features during the past five years of prosecution, is an implied acknowledgment of the patentability of this application.

A. The Claims Are Patentable Over Bernstein

1. Bernstein Does Not Teach Applying Lipid Concentrates Topically As A Biodermal Fraction Representing 98-100% By Weight Of The Composition

Bernstein does not teach applying lipid concentrates topically as a biodermal fraction representing 98-100% by weight of the composition. Bernstein teaches a traditional dermatological product that is differentiated from the subject matter of the pending claims in that the pending claims recite a product made of components that cannot be classified or distributed between an active fraction ("active principle") and an inactive fraction ("excipient"). As recited in pending claim 1, 98-100% of the components behave as an active

principle, *e.g.*, treating the skin. The excipient creates a suitable and stable topical form for the application of the product, but does not contribute to the treatment of the skin.

Bernstein, addressing a traditional dermatological product teaches non-biodermal constituents ranging from 38% to 40%, as illustrated by Examples 1 and 2, and Formulas 1-3. Therefore, the biodermal fraction, by weight of the composition is in the range of 60-62%.

In accordance with MPEP §2131.03, "[p]rior art which teaches a range overlapping or touching the claimed range anticipates if the prior art range discloses the claimed range with 'sufficient specificity'." Appellant submits that the claimed range, of from 98-100% of the biodermal constituent, or 0-2% of the non-biodermal fraction, does not touch, nor overlap, any range as taught by Bernstein, *i.e.*, 60-62% of the biodermal fraction, and 38-40% of the non-biodermal fraction.

Further, for example, Example 1 of Bernstein (col. 2, lines 24-49) teaches that the lipid concentrate is 10% by weight (active principle), and the excipient is 90% by weight. Therefore, as illustrated above, and further illustrated by Example 2, and Formulas 1-3, and Formula 2 with vitamin E, Bernstein cannot reasonably be considered to teach a biodermal fraction representing 98-100% by weight of the composition, or a non-biodermal fraction representing 0-2% by weight of the composition, as positively recited in the claims.

Bernstein discloses in col. 2, lines 18-20, that "the resulting lipid concentrate formulation may be then added to cream, ointment, gel or lotion vehicles, [*i.e.*, an excipient]," thereby, even further reducing the weight percentage of the active ingredient.

For at least the above reasons, Bernstein cannot reasonably be considered to teach, or to have suggested, the combination of all of the features recited in at least independent claim 1. Claims 2, 3, 5-8, 12, 16, 18-20, 23 and 29 also are not taught, nor would they have been suggested by the Bernstein for at least the respective dependence of these claims on allowable

independent claim 1, as well as for the separately patentable subject matter that each of these claims recite.

2. **Bernstein Does Not Teach That, If Water Is One Of The Constituents, It Is Part Of The Biodermal Fraction And Represents A Minor Part By Weight Of Said Composition**

The Office Action asserts that Bernstein teaches using water in an amount of 50%. The Office Action, however, concludes that a skilled artisan would have been motivated to optimize the specific amount to below 50% in attempting to render obvious the subject matter of claim 1. The analysis of the Office Action fails for at least the following reasons.

Claim 1 recites that "if water is one of the constituents, it is part of the biodermal fraction and represents a minor part by weight of said composition." Thus, if water is present, it is part of the fraction that exerts a beneficial action or result on an exterior portion of the human body. Bernstein discloses therapeutic formulations of lipid concentrates (active principle) made without water. Bernstein's active ingredient is subsequently mixed with the water containing vehicle. Accordingly, Bernstein teaches water as a component of the excipient and not of the biodermal fraction (active principle), as recited in claim 1.

Further, even if Bernstein were to disclose water as one of the constituents of the active principle, the Office Action fails to demonstrate that a skilled artisan would be motivated to vary the therapeutic formulations of Bernstein. The Office Action, in its conclusory statement that such would have been obvious, not only must ignore the positive discussion in Appellant's disclosure, for example on page 3, lines 8-14, but must also apply improper hindsight reasoning based on Appellant's disclosure in order to assert that subject feature would have been obvious. Additionally, the Office Action must also ignore Federal Circuit precedent that "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988

(Fed. Cir. 2006). Specifically, Formula 3 in Bernstein discloses 50 % water by weight. All the other Formulas disclose higher water contents. Bernstein, in the second table in col. 4, teaches that Formula 3 is slightly less efficient than Formula 1 and Formula 2, both having higher water content, in preventing evaporative water loss. Thus, a skilled artisan would not be motivated to further reduce the water content of the vehicle in Bernstein. If anything, a skilled artisan would try to optimize the water content around 51%, which is the content of the most efficient formulation for preventing water loss based on the disclosure of Bernstein. Finally, water content is not properly shown to be a result-effective variable nor would one skilled in the art consider it to be based on the disclosure that the water content of Formulas 1-3 in Bernstein does not change the prevention of water loss by more than 0.2 percentage points. Without establishing this necessary pre-condition, the Office Action has no basis to assert that the variable may be optimized through routine experimentation.

As discussed previously, Bernstein fails to render obvious the subject matter of the pending claims for at least its failure to teach, or even to have suggested, a biodermal fraction representing 98-100% by weight of the composition, and/or a non-biodermal fraction representing 0-2% by weight of the composition, as positively recited in the pending claims.

For at least the above reasons, Bernstein cannot reasonably be considered to teach, or to have suggested, the combination of all of the features recited in at least independent claim 1. Further, claims 9-11 and 13 would also not have been suggested by the applied prior art references for at least the respective dependence of these claims on allowable independent claim 1, as well as for the separately patentable subject matter that each of these claims recites.

B. Yu Does Not Cure The Deficiencies Of Bernstein With Respect To The Pending Claims

The Office Action concedes that Bernstein and Yu, in any permissible combination, do not teach the weight amounts of the composition recited in claim 1. The Office Action asserts that the "amount of a specific ingredient is clearly a result effective parameter," without giving any further explanation.

In attempting to justify the rejection of at least independent claim 1, as being obvious under Bernstein and Yu, the Office Action incorrectly attempts to classify the range of the biodermal, and non-biodermal constituents, as recognized in the applied references as result-effective variables. This assertion fails for at least the following reason.

MPEP §2144.05.II.A, in citing court precedent, states "[w]hen the general conditions of a claim are disclosed in the prior art, it is *not inventive to discover the optimum or workable ranges by routine experimentation.*" *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Appellant submits that the general conditions of the claim are not disclosed in the prior art for at least the reasons as discussed above. Specifically, Bernstein and Yu teach a traditional cosmetic product having significantly more excipient than that recited in the pending claims.

Additionally, neither prior art reference recognizes the "by weight" percentage of the biodermal and the non-biodermal constituents as result-effective variables, nor is such an assertion supported by any other objective evidence of record. Specifically, Bernstein teaches that the lipid concentrate formula may be added to cream, ointment, gel or lotion vehicles in weight/weight concentrations ranging from about 1% to 50%, thereby clearly demonstrating that Bernstein did not consider biodermal concentrations, exceeding 50%, as being beneficial to the treatment and prevention of dry skin.

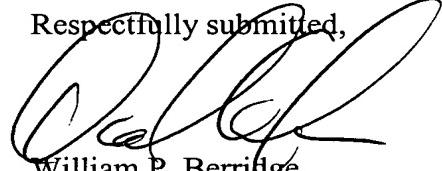
Additionally, Yu teaches the active principle is a mixture of (1) an amphoteric or pseudo-amphoteric agent, such as certain metallic oxides such as aluminum oxide and zinc oxide (col. 3, lines 45-46), and (2) an acyclic ester of an hydroxyacid (claim 1). The active principle is then mixed with a vehicle, or excipient, to obtain a final dermatological product (col. 2, lines 36-62). Therefore, Yu does not teach that the by weight concentrations are result-effective variables, with respect to the pending claims, as asserted in the Office Action, as Yu does not teach a bio-dermal fraction. Bio-dermal being defined in Appellant's disclosure as being any component or product forming part of the composition of the skin, so that it remains cytocompatible with the skin. Yu describes topical substances.

For at least the above reasons, Bernstein and Yu, in any permissible combination, cannot reasonably be considered to teach, or to have suggested, the combination of all of the features recited in at least independent claim 1. Further, claims 9-11, 16, 21 and 22 would also not have been suggested by the applied prior art references for at least the respective dependence of these claims on allowable independent claim 1, as well as for the separately patentable subject matter that each of these claims recite.

VIII. CONCLUSION

For all of the reasons discussed above, it is respectfully submitted that the asserted prior art rejections of the pending claims are in error, and that claims 1-3, 5-8, 12, 16, 18-20, 23 and 29 are in condition for allowance. For all of the above reasons, Appellants respectfully request that this Honorable Board reverse the rejections of claims 1-3, 5-8, 12, 16, 18-20, 23 and 29.

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APPENDIX A - CLAIMS APPENDIX

CLAIMS INVOLVED IN THE APPEAL:

1. A cosmetic or dermo-therapeutic composition for a direct application onto surface parts of the human body, in a form adapted for said direct application, said composition comprising:

a biodermal fraction representing 98-100% by weight of the composition, comprising at least two different biodermal constituents, each being cytocompatible with skin; and

a non-biodermal fraction representing 0-2% by weight of the composition, comprising at least one non-biodermal constituent that is compatible with skin, said composition having no excipient or vehicle adapted to said form of the composition,

wherein, if water is one of the constituents, it is part of the biodermal fraction and represents a minor part by weight of said composition.

2. The composition according to claim 1, wherein at least one of the biodermal constituents are biomimetic with a component of skin.

3. The composition according to claim 1, wherein each of said biodermal constituents are biomimetic with a component of skin.

4. (Canceled)

5. The composition according to claim 1, wherein a major portion of said composition consists of one or more constitutive components of skin.

6. The composition according to claim 1, wherein each biodermal constituent is selected from the group consisting of biological, mineral, organic or biochemical species or entities of which the epidermis or the dermis is composed.

7. The composition according to claim 1, wherein at least one of said biodermal constituents is a skin nutrient.

8. The composition according to claim 1, wherein said composition comprises at least one non-biodermal constituent that is cytocompatible with skin.

9. The composition according to claim 1, wherein said composition is in a two-phase form.

10. The composition according to claim 9, wherein said composition is a water-in-oil dispersion.

11. The composition according to claim 9, wherein said composition is an oil-in-water dispersion.

12. The composition according to claim 1, consisting of biodermal constituents that are cytocompatible with skin.

13. The composition according to claim 1, comprising water.

14-15. (Canceled)

16. The composition according to claim 1, wherein each constituent is selected from the group consisting of:

(a) substantially cytocompatible and/or bioassimilable components present in constitutional form in the skin;

(b) macromolecular components of the skin;

(c) components assimilable by the skin; and

(d) inert components with respect to skin.

17. (Canceled)

18. A cosmetic method, comprising topically applying a composition according to claim 1 to skin of a human.

19. The method according to claim 18, wherein at least one of the biodermal constituents of said composition are biomimetic with a component of said skin.

20. The method according to claim 18, wherein a major portion of said composition consists of one or more constitutive components of skin.

21. The composition according to claim 1, wherein said at least two biodermal constituents include at least one amino acid.

22. The composition according to claim 21, wherein said composition comprises at least one non-biodermal trace element.

23. The composition according to claim 5, wherein said composition further comprises at least one skin nutrient.

24-28. (Canceled)

29. The composition according to claim 1, wherein a minor portion of said composition consists of a skin nutrient.

30-35. (Canceled)

APPENDIX B - EVIDENCE APPENDIX

NONE

APPENDIX C - RELATED PROCEEDINGS APPENDIX

NONE